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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,165	03/18/2004	Edgardo Costa Maiani	DID1047US	7387

9561 7590 06/01/2006

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EXAMINER

CRAIG, PAULA L

ART UNIT PAPER NUMBER

3761

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/805,165	Applicant(s) MAIANTI ET AL.	
	Examiner Paula L. Craig	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because of the informalities indicated on the enclosed Form PTO-948. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: On page 1, line 7, the number of the copending application must be supplied. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 6, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,770,149 to Raible.

5. For Claim 1, Raible '149 teaches an integrated device for oxygenating and filtering blood flowing through an extracorporeal blood circuit (Abstract and Figs. 1-9a). Raible teaches a blood reservoir having an inlet for receiving venous blood and an outlet for supplying venous blood (reservoir 111, Abstract, Figs. 8-8a and col. 12, lines 6-42). A blood pump has an inlet connected to receive blood from the outlet of the blood reservoir, and an outlet (Figs. 3, 8, and 8a and col. 12, lines 37-51). Raible teaches a heat exchanger having a blood inlet connected to receive venous blood from the outlet of the pump and a blood outlet for supplying temperature controlled venous blood (Fig. 3 and 8a, col. 7, lines 1-67, and col. 12, lines 49-52). An oxygenator has an

Art Unit: 3761

inlet connected to receive venous blood from the outlet of the heat exchanger and an outlet for supplying oxygenated blood (Fig. 3 and col. 8, lines 1-41). Raible teaches an arterial blood filter having an inlet connected to receive oxygenated blood from the outlet of the oxygenator and an outlet for supplying filtered oxygenated blood (Abstract, Figs. 9-9a, col. 12, line 54 to col. 13, line 41, and col. 15, lines 17-24). Raible shows a monolithic housing including a first portion for defining the blood reservoir, a second portion for defining the blood pump, a third portion for defining the heat exchanger, a fourth portion for defining the oxygenator and a fifth portion for defining the arterial blood filter (Figs. 1-3, 8, 8a, 9, and 9a, col. 5, line 44 to col. 6, line 10, and col. 12, line 6 to col. 13, line 40, and col. 13, line 60 to col. 15, line 24).

6. For Claim 6, Raible '149 teaches a system for establishing an extracorporeal blood circuit (Abstract and Figs. 1-9a). Raible teaches a blood reservoir, a blood pump, a heat exchanger, an oxygenator, and an arterial blood filter (Abstract, Figs. 3, 8, 8a, col. 8, lines 1-41, col. 12, line 6 to col. 13, line 41, and col. 15, lines 17-24). Raible teaches a housing for incorporating and interconnecting the blood reservoir, the blood pump, the heat exchanger, the oxygenator and the arterial blood filter into a monolithic structure, the housing having an inlet for supplying venous blood to the blood reservoir and an outlet for supplying oxygenated blood from the arterial blood filter (Figs. 1-3, 8, 8a, 9, and 9a, col. 5, line 44 to col. 6, line 10, and col. 12, line 6 to col. 13, line 40, and col. 13, line 60 to col. 15, line 24).

7. For Claims 2 and 7, Raible '149 teaches the blood pump being a centrifugal pump (Figs. 3 and 8, col. 10, line 38 to col. 12, line 52).

8. For Claims 4 and 9, Raible '149 teaches the blood reservoir including a venous reservoir and a cardiectomy reservoir (Figs. 8-8a and col. 12, lines 6-35).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raible '149 in view of U.S. Patent No. 5,924,848 to Izraelev.

12. For Claims 3 and 8, Raible '149 teaches all the limitations of Claims 2 and 7, as described above in paragraph 7. Raible teaches the centrifugal pump having an axis, and the centrifugal pump being positioned within the monolithic housing (Figs. 3 and 8a). Raible '149 does not teach the axis of the centrifugal pump being horizontal. Izraelev teaches a centrifugal pump for pumping human blood in which the axis of the pump may be horizontal or vertical (Figs. 1-3 and col. 3, lines 52-59). The pump of

Izraelev is designed to be stable when the direction of the pump's axis of rotation is changed because the position of the housing is changed (col. 3, lines 52-59). It would have been obvious to one of ordinary skill in the art to modify Raible '149 to include the axis of the centrifugal pump being vertical or horizontal, as taught by Izraelev, to provide for flexibility in positioning the pump, as taught by Izraelev.

13. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raible '149 in view of U.S. Patent No. 6,306,346 to Lindsay.

14. For Claims 5 and 10, Raible '149 teaches all the limitations of Claims 4 and 9, as described above in paragraph 8. Raible '149 does not teach the housing including connection means for allowing removable connection of the first portion. However, removable reservoirs are well known in the art. Lindsay '346 confirms this and teaches an integrated device for oxygenating and filtering blood flowing through an extracorporeal blood circuit including a blood reservoir for venous blood, a blood pump, a heat exchanger, an oxygenator, and a monolithic housing (Abstract, Figs. 2, 4, and 7, col. 3, lines 33-38, col. 4, lines 1-60, and col. 5, lines 9-46). Lindsay teaches the monolithic housing including connection means for allowing removable connection of the first portion (col. 5, line 62 to col. 6, line 24). Lindsay teaches that the removable connection allows the reservoir to be removed during surgery if necessary without removing the oxygenator (col. 5, line 65 to col. 6, line 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Raible to include connection means for allowing removable connection of the first portion, as taught by

Lindsay, to allow the reservoir to be removed during surgery if necessary without removing the oxygenator, as taught by Lindsay.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1, 2, 4, 5, 6, 7, 9, and 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-5 of U.S. Patent No. 6,723,283 to Ghelli. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the Ghelli patent include all of the claimed limitations except for the blood reservoir, the centrifugal blood pump, and the removable connection. However, these elements are all well known in the art.

17. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-6 of copending Application No. 10/804,583 to Maianti et al or Claims 1-10 of copending Application No. 10/614,722 to Maianti et al., each individually. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '583 application include all the claimed elements except for the blood reservoir for receiving venous blood. However, the claims of the '583 application include a bubble trap for receiving venous blood, which is equivalent to a blood reservoir for receiving venous blood. The claims of the '722 application include all the claimed elements, including a venous blood reservoir and a heat exchanger, except that the claims of the '722 application do not include the heat exchanger supplying temperature controlled venous blood. However, this is well known in the art. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 2,319,730 to Garraway shows a centrifugal pump that can be used in a horizontal position. U.S. Patent Nos. 2,659,368 to Gibbon, Jr., et al., 4,490,331 to Steg, Jr., 4,610,656 to Mortensen, 5,308,320 to Safar et al., 5,391,142 to Sites et al., and Statutory Invention Registration No. H1324 show integrated devices for oxygenating and filtering blood in an extracorporeal blood circuit

Art Unit: 3761

with monolithic housings. U.S. Patent No. 6,451,257 to Flamer shows an arterial blood filter. The remaining prior art references listed on the accompanying Form PTO-892 show the general state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571)272-5964. The examiner can normally be reached on 8:30AM-5:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571)272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paula L Craig
Examiner
Art Unit 3761

PLC

RECEIVED
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